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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,111	08/04/2003	Peter Redinger	QC-0108 (1502-82)	6388

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EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT	PAPER NUMBER
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3763

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/19/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.		Applicant(s)	
	10/634,111		REDINGER, PETER	
	Examiner		Art Unit	
	Christopher D. Koharski		3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Examiner acknowledges the reply filed Applicant on 10/18/2006 in which claims 1, 13 and 20 are amended and new claims 21-26 being added. Currently claims 1-26 are pending for examination in this application.

Response to Arguments

Applicant's arguments filed 10/18/2006 have been fully considered but they are not persuasive. Regarding the Twardowski et al. reference (5,569,182) Applicant's representative asserts the that catheter is not dimensioned and positioned to engage interior wall portions of the blood vessel in supporting relation therewith to substantially minimize collapse of the vessel wall and occlusion of at least one lumen. Examiner asserts that this limitation is functional and therefore the structure and design of Twardowski et al. is capable meeting this limitation due to the ridges and lumen design. Thus, where the prior art reference is inherently capable of performing the function described in a functional limitation, such functional limitation does not define the claimed apparatus over such prior art reference, regardless of whether the prior art reference explicitly discusses such capacity for performing the recited function, see *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971). Regarding the Mahurkar (5,221,256) reference, Applicant's representative asserts that the reference fails to show a plurality of ridges/pair of ridges. Examiner asserts that the ridges of Mahurkar are defined by the lateral opening elements that facilitate the opening recess and thus meet the claim limitation. As asserted above, Examiner also contends that the Mahurkar reference in

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capable of meeting the functional limitation drawn to the dimension and size of the catheter for vascular support (see above).

In the interest of furthering prosecution Examiner also hereby submits original/additional claim rejections upon the claims (see below) that address the current amended and new claims added.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Twardowski et al. (5,569,182). Twardowski et al. discloses a clot resistant catheter.

Regarding claims 1 and 2, Twardsowki et al. discloses a catheter comprising an elongate body extending from a proximal to distal end that is dimensioned and positioned to engage interior wall portions of the blood vessel in supporting relation therewith to substantially minimize collapse of the vessel wall and occlusion of at least one lumen and capable of being inserted into the vasculature and comprises a first and second wall that define at least one lumen (65,67) wherein a ridge extends from the wall and defines a lateral opening and extends substantially to the distal end of the body (Figures 8-12).

Claim Rejections - 35 USC § 102

Claims 1-3, 13-14, 21-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Seder et al. (5,116,310). Seder et al. discloses a multiple lumen wound drainage catheter.

Regarding claims 1-3, 13-14 and 21-26, Seder et al. discloses a catheter comprising an elongate body (30) with a proximal and distal end defining a longitudinal axis, the elongated body having an outer wall defining at least one lumen (32, 34, 36) through the elongate body, the outer wall having a lateral opening (40, 42) that is communication with the outer wall defining a pair of ridges (24, 44) that are adjacent the lateral opening and are capable being positioned to engage interior wall portions of the blood vessel in supporting relation therewith to substantially minimize collapse of the vessel wall and occlusion of at least one lumen (Figures 1-2). In addition the outer wall formed ridges extend the to the distal end of the elongate body defined by a substantially planar septum (inner wall) are arranged by oblique angles to the longitudinal axis (Figures 1-2).

Claim Rejections - 35 USC § 102

Claims 13-17 and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Mahurkar (5,221,256). Mahurkar discloses a multiple-lumen catheter.

Regarding claims 13-17 and 19-20, Mahurkar discloses a an elongated body with extending from a proximal to distal end, the elongated body having an outer wall and inner wall with multiple lumens (13-15) and multiple ports (22, 25 Figure 18) with multiple pairs of ridges (80, 81) defining lateral openings that are capable being

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positioned to engage interior wall portions of the blood vessel in supporting relation therewith to substantially minimize collapse of the vessel wall and occlusion of at least one lumen (Figures 18-21).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Lotito et al. (7,090,654). Lotito et al. discloses a blood flow catheter.

Regarding claims 1 and 13, Lotito et al. discloses a catheter comprising an elongate body (12) with a proximal and distal end defining a longitudinal axis, the

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elongated body having an outer wall defining at least one lumen (16, 18) through the elongate body, the outer wall having a lateral opening (38, 40, 42, 44) that is in communication with the outer wall defining a pair of ridges (314, 316, 332, 364) that are adjacent the lateral opening and are capable being positioned to engage interior wall portions of the blood vessel in supporting relation therewith to substantially minimize collapse of the vessel wall and occlusion of at least one lumen (Figures 10-15). In addition the outer wall formed ridges extend to the distal end of the elongate body defined by a substantially planar septum (inner wall) are arranged by oblique angles to the longitudinal axis (Figures 10-15).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3-8 and 10-12 are rejected under 35 U.S.C 103(a) as being unpatentable over Twardoski et al. in view of Mahurkar. Twardoski meets the claim limitations as

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described above but does not include ports and a third lumen.

However, Mahurkar teaches a multiple-lumen catheter. Regarding claims 3-8 and 10-12, Mahurkar teaches an elongated body with multiple ports, lumens, walls and ridges that extend from the walls such that distance of the ridges and lumens is configured to support a vessel wall in the manner claimed (Figures 18-21). At the time of the invention, it would have been obvious to use the additional lumens and side holes of Mahurkar with the system of Twardowski et al. because the addition of the additional lumen and the plural side holes allows for additional flow through the catheter and additional lumens for drug delivery. Moreover it would have been obvious to one having ordinary skill in the art at the time the invention was made to add additional lumens, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art, see *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8 (CA7 1977).

Both references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Mahurkar.

Claim Rejections - 35 USC § 103

Claims 9 and 18 are rejected under 35 U.S.C 103(a) as being unpatentable over Twardoski et al. in view of Mahurkar in further view of Spehalski (6,099,513). The modified Twardoski meets the claim limitations as described above but does not include multiple lateral elements.

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However, Spehalski teaches a wound drain with alternating perimetrically arranged lumens. Regarding claims 9 and 18, Spehalski teaches catheter with ridges and lateral channels (Figure 8). At the time of the invention, it would have been obvious to use the ridges and lateral channels of Spehalski with the system of the modified Twardoski et al. because the addition of lateral channels allows for better flow through and along the catheter body. Both references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Spehalski.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 12/2/2006


Christopher D. Koharski
AU 3763

